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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,901	02/09/2001	Charlene A. Boehm	46607-248184	6758

7590 03/09/2004

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Winston-Salem, NC 27101-2400

EXAMINER

MARSCHER, ARDIN II

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,901

Applicant(s)

BOEHM, CHARLENE A.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 12/9/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

VAGUENESS AND INDEFINITENESS

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, the method is directed to determining therapeutic resonant frequencies thus indicating that the resonance is meant to be utilized during therapeutic procedures. Such procedures apparently will thus be administered to a patient. Confusingly, none of the determinations of frequencies in the actual method steps are directed to patient parameters. The electromagnetic radiation with the therapeutic frequencies are well known to be influenced by the medium in which it is traveling through, both in velocity and wavelength. Solid, semi-solid, or liquid media, for example, support a different velocity of electromagnetic radiation depending on its exact content. It is therefore unclear whether the preamble controls the metes and bounds of the claims wherein the method would be limited to performance inside of a patient or whether unlimited determinations of wavelength etc. are meant as in the claim steps.

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Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 also contain this unclarity due to their dependence.

LACK OF ENABLEMENT

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Reconsideration of the instant disclosure regarding frequency determinations in the claims reveals that the wavelength value which is utilized in the instant invention for said frequency determination lack enablement.

Regarding the wavelength which determines the resonant frequency for genomic material as applied to therapeutic use, the electromagnetic radiation of the claimed method is applied to target genomic material for therapy. The instant claims indicate that the wavelength of the genomic material is either a known quantity or determined via utilizing the average spacing of base pairs of nucleic acid as in claim 1, for example. The average spacing of base pairs has been previously determined via crystallized nucleic acid material in an X-ray crystallography technique as summarized in Lehninger on pages 638-641. This material, however, is highly purified nucleic acid and free of histones and a plethora of proteins and RNAs compared to such genomic material in a therapeutic situation where living cells are being treated. Such genomic material is discussed in Lehninger on pages 642—644 as being an enormous molecule or molecules depending on the organism being described. Even for simpler bacteria such as *E. coli* Lehninger on page 644, lines 6-11, the enormous DNA molecule is packed into a relatively small volume in a nuclear zone. Figure 28-8 on page 644 shows a single human chromosome which is exceedingly complex and convoluted as well as supercoiled. On page 644 a mammalian cell is stated as having more than 10^9 base pairs. Thus, the receiving of electromagnetic radiation is based on a genomic material form which is very complex.

Electromagnetic radiation is received by antennas which are utilized in radio systems. The enclosed section of an antenna information book is enclosed to illustrate the wavelength and other antenna issues which determine such electromagnetic radiation absorption. Chapter 2 on pages 25-66 of the The ARRL Antenna Book set forth antenna fundamentals for various types of electromagnetic radiation antenna systems. The majority of said Chapter 2 describes the radiation of electromagnetic energy, however, on page 36, lefthand column, second full paragraph, the properties of a resonant antenna used for reception and transmission are the same for all practical purposes thus making the parameters practically equivalent for the radiation discussions in said Chapter and radiation absorption such as in the therapy as instantly claimed. It, however, is noted that antenna characteristics are quite complex even for the linear type antennas with some dipoles and other minor variations described in said chapter 2. The electrical length of a linear antenna is not necessarily the same as its physical length as noted on page 27, lefthand column, lines 14-19. It is noted that this leaves the instant calculation of genomic material length vs. its electrical length for wavelength purposes inaccurate. On page 28, Figure 2-4 shows that the half wave length varies depending on the length/diameter ratio of the antenna. On page 32, a section entitled "Coupled Antennas" describes added complexity that occurs when antenna sections are close enough for coupling. Clearly a closely packed genomic material content of a cell will have such coupling effects. Polarization effects are described starting on page 35. Radiation and thus equivalently electromagnetic energy absorption patterns are discussed and shown on pages 37-66 including loop antennas

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which is described in Lehninger as being the genomic type material in bacteria. In summary, the simplistic wavelength calculation as set forth in the instant application ignores these complexities even if the genomic material was linear in nature. This simplifying situation, however, is clearly not the case in therapy situations wherein the genomic material is in a complex nuclear region in cells, closely packed so that there are billions literally of linear sections which are couples and may be in loops. Thus, it would clearly require undue experimentation to determine a wavelength for genomic material in a therapeutic setting and thus prevents the determination of wavelength with any reasonable accuracy for the practice of the instant invention. It is noted that a resonant frequency calculation as set forth in the instant claims requires such a wavelength determination or calculation and thus equivalently lacks enablement without undue experimentation.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

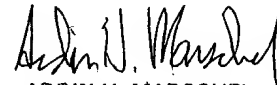
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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

March 5, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER